

1 Student's t test. Dichotomous data are subjected to  
2 CHi square of Fisher's exact test, as is appropriate.

3 A power analysis was done to determine the number  
4 of patients in each test group in order to show  
5 predicted differences. Power analysis applied to an  
6 ANOVA using a power of 0.80 with  $\alpha = 0.05$ , coupled with  
7 prior studies of mean ALT levels and their variances,  
8 estimated a need for 21 to 52 patients in each test  
9 group to show a mean ALT difference of 15 IU/L. As 3  
10 to 5% of patients are expected to drop out, and  
11 factoring in treatment of the control group after six  
12 months, 40 patients per group was arrived at.

13 We Claim:

14 1. A method of treating a mammal infected with  
15 hepatitis C virus, comprising administering to said  
16 mammal an anti-viral effective amount of at least one  
17 interferon, concurrently or sequentially with  
18 administering said thymosin or thymosin fragment.

19 2. A method of Claim 1, wherein said interferon  
20 is selected from the group consisting of  $\alpha$ -,  $\beta$ - and  $\gamma$ -  
21 interferons.

22 3. A method of Claim 2, wherein said  $\alpha$ -interferon  
23 is interferon  $\alpha$ -2b.

24 4. A method of Claim 1, wherein the step of  
25 administering said interferon comprises administering  
26 interferon produced by recombinant DNA technology.

10. A composition of Claim 9, wherein said  $\alpha$ -  
interferon is interferon  $\alpha$ -2b.

Sub. B2

Sub  
27

[illegible]

Sub. B3

22  
23 16. An anti-hepatitis C formulation comprising an  
24 immune system-potentiating amount of at least one  
25 thymosin or an immune system-potentiating thymosin  
26 fragment in combination with an anti-viral effective

Sub B3  
As  
1 amount of at least one interferon in a pharmaceutically  
2 acceptable carrier, for use in the treatment of a  
3 mammal infected with hepatitis C virus.

4 17. The formulation of claim 16, wherein said  
5 thymosin is selected from the group consisting of  
6 Thymosin Fraction Five and Thymosin  $\alpha$ -1.

7 18. The formulation of Claim 16, wherein said  
8 interferon is selected from the group consisting of  $\alpha$ -,  
9  $\beta$ -, and  $\gamma$ -interferons.

10 19. The formulation of Claim 18, wherein said  $\alpha$ -  
11 interferon is interferon  $\alpha$ -2B.

12 20. The formulation of Claim 19, wherein said  
13 interferon is recombinant interferon.

14 21. The formulation of Claim 16, wherein said  
15 thymosin is Thymosin Fraction Five, said immune system-  
16 potentiating amount is a human immune system-  
17 potentiating amount, and said amount is from about 900  
18 to about 1200 mg/m<sup>2</sup> body surface area of said human.

19 22. The formulation of Claim 16, wherein said  
20 interferon is  $\alpha$ -interferon and wherein said anti-viral  
21 effective amount is from about 1 million to about 3  
22 million units of said interferon.

23 23. The formulation of Claim 16, wherein said  
24 thymosin is Thymosin  $\alpha$ -1, said immune system-  
25 potentiating amount is a human immune system-

[illegible]

3            24. The formulation of Claim 16, wherein said  
4            thymosin is Thymosin  $\alpha$ -1, and wherein said amount is  
5            about 1500 to about 1700  $\mu$ g of Thymosin  $\alpha$ -1.